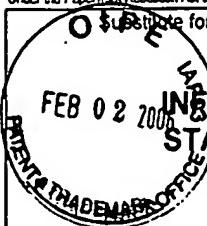


Please type a plus sign (+) inside this box →

PTO/SB/03A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

O Substitute for form 1449A/PTO		Complete if Known	
 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number 10/663,265 Filing Date September 16, 2003 First Named Inventor Edith Mathiowitz Group Art Unit 1633 Examiner Name Maria Gomez Leavitt Attorney Docket Number BU MAT1993-04fDIV3CON2	
Sheet	1	of	6

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
ML	4,272,398			Jaffe	06-09-1981	
	4,775,624			Bang, et al.	10-04-1988	
	4,861,627			Mathiowitz, et al.	08-29-1989	
	4,863,735			Kohn, et al.	09-05-1989	
	4,897,355			Eppstein, et al.	01-30-1990	
	4,898,734			Mathiowitz, et al.	02-06-1990	
	5,100,669			Hyon, et al.	03-31-1992	
	5,100,792			Sanford, et al.	03-31-1992	
	5,171,217			March, et al.	12-15-1992	
	5,271,961			Mathiowitz, et al.	12-21-1992	
	5,366,881			Singh, et al.	11-22-1994	
	5,639,473			Grinstaff, et al.	06-17-1997	
	5,643,578			Robinson, et al.	07-01-1997	
	5,674,192			Sahatjian, et al.	10-07-1997	
	5,763,416			Banadio, et al.	06-09-1998	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
	EP	0-248-531		Southern Research Institute	12-09-1987		
	EP	0-330-180		Biomaterials Universe, Inc.	08-30-1989		
	EP	0-302-582		Southern Research Institute	02-08-1989		
	EP	5 79347		Ferring-Arzneimittel, GMBH	01-19-1994		
	PCT	WO 93/0885		Massachusetts Institute of Technology	05-123-1993		

Examiner's Signature	<i>Maria Leavitt</i>	Date Considered	<i>03-20-06</i>
----------------------	----------------------	-----------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			
		Application Number	10/663,265
		Filing Date	September 16, 2003
		First Named Inventor	Edith Mathiowitz
		Group Art Unit	1633
		Examiner Name	Maria Gomez Leavitt
		Attorney Docket Number	BU MAT1993-04fDIV3CON2
Sheet	2	of	6

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁸
		Office ²	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 93/21906		Brown University Research Foundation	11-11-1993		
		PCT	WO 93/25221		Alkermes Controlled Therapeutics	12-23-1993		
ML		PCT	WO 94/23699		Medisorb Technologies International LP	10-27-1994		
		PCT	WO 94/23738		Medisorb Technologies International LP	10-27-1994		

Examiner's Signature	luaric deauitt	Date Considered	03-20-06
----------------------	----------------	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/663,265
Sheet	3	of	6	Filing Date	September 16, 2003
				First Named Inventor	Edith Mathlowitz
				Group Art Unit	1633
				Examiner Name	Maria Gomez Leavitt
				Attorney Docket Number	BU MAT1993-04fDIV3CON2

OTHER ART – NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		ACSADI, et al., "Human dystrophin expression in mdx mice after intramuscular injection of DNA constructs", <i>Nature</i> , 352(6338):815-8 (1991).
		BENITA, et al., "Characterization of drug-loaded poly(D,L-lactide) microspheres", <i>J Pharm Sci</i> , 73(12):1721-4 (1984).
		BLAU, "Muscular dystrophy: Muscling in on gene therapy", <i>Nature</i> , 364(6439):673-5 (1993).
		CHANGBEN and SHOUYUJAN, "Use of human erythrocyte ghosts for transfer of 125I-BSA and 125I-DNA into animal cells through cell fusion", <i>Scientia Sinica</i> , XXV(8):860-865 (1982).
		COGHLAN, et al., "Gene dream fades away", <i>New Sci</i> , 148(2005):14-5 (1995).
		COHEN, "Naked DNA points way to vaccines", <i>Science</i> , 259(5102):1691-2 (1993).
		CLARK, "Overview and general considerations of wound repair", in <i>The Molecular and Cellular Biology of Wound Repair</i> eds. R Clark and P Henson, pp 3-33 1988.
		CRYSTAL, "Transfer of genes to humans: early lessons and obstacles to success", <i>Science</i> , 270(5235):404-10 (1995).
		DAGANI, "Gene therapy advance: anti-HIV antibodies work inside cell", <i>Chemical & Engineering News</i> , pp 3-4 (1993).
		DUNCAN, "Drug-polymer conjugates: potential for improved chemotherapy", <i>Anticancer Drugs</i> , 3(3):175-210 (1992).
		EISENBERG and CROTHERS, (eds) "Physical Chemistry with Application to the Life Sciences", Benjamin/Cummings Publishing CO., Menlo Park, CA, p705, 1979.

Examiner's Signature	<i>Maria Leavitt</i>	Date Considered	03-20-06
----------------------	----------------------	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/03A (10-95)
Approved for use through 10/01/99. OMB 0651-0031
Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/663,265
Sheet	4	of	6	Filing Date	September 16, 2003
				First Named Inventor	Edith Mathiowitz
				Group Art Unit	1633
				Examiner Name	Maria Gomez Leavitt
				Attorney Docket Number	BU MAT1993-04fDIV3CON2

OTHER ART – NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		EISENBERG, et al., "Examination of parameters affecting the elicitation of humoral immune responses by particle bombardment-mediated genetic immunization", <i>DNA Cell Biol.</i> , 12(9):791-7 (1993).
		FYNAN, et al., "DNA vaccines: protective immunizations by parenteral, mucosal, and gene-gun inoculations" <i>Proc Natl Acad Sci U S A.</i> , 90(24):11478-82 (1993).
		HAWLEY-NELSON, et al., "Lipofectamine reagent: A new higher efficiency polycationic liposome transfection reagent", <i>Focus</i> , 15:73-8 (1993).
		HENSYL, et al. (eds) "Stedman's Medical Dictionary", 25 th edition, Williams and Wilkins, Baltimore, MD. P 1473, 1990.
		JIAO, et al., "Persistence of plasmid DNA and expression in rat brain cells in vivo", <i>Exp Neurol.</i> , 115(3):400-13 (1992).
		KAY, et al., "In vivo gene therapy of hemophilia B: sustained partial correction in factor IX-deficient dogs", <i>Science</i> , 262(5130):117-9 (1993).
		LEDLEY, "Nonviral gene therapy: the promise of genes as pharmaceutical products", <i>Hum Gene Ther.</i> , 6(9):1129-44 (1995).
		LIM, et al., "Microencapsulation of living cells and tissues", <i>J Pharm Sci.</i> , 70(4):351-4 (1981).
		MARX, "A first step toward gene therapy for hemophilia B?", <i>Science</i> , 262(5130):29-30 (1993).
		MATHIOWITZ, et al., "Polyanhydride microspheres. IV. Morphology and characterization of systems made by spray drying", <i>J. Appl Polymer Sci.</i> , 45:125-34 (1992).
		MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems", <i>Scanning Microsc.</i> , 4(2):329-40 (1990).

Examiner's Signature	<i>Maria Leavitt</i>	Date Considered	03-20-06
----------------------	----------------------	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/663,265
Sheet	5	of	6	Filing Date	September 16, 2003
				First Named Inventor	Edith Mathiowitz
				Group Art Unit	1633
				Examiner Name	Maria Gomez Leavitt
				Attorney Docket Number	BU MAT1993-04fDIV3CON2

OTHER ART – NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		MATHIOWITZ, et al., "Polyanhydride microspheres II. Microencapsulation by solvent removal", <i>J. Appl. Polymer Sci.</i> , 35:755- (1988).
		MATHIOWITZ, et al., "Polyanhydride microspheres I. Hot-melt microencapsulation", <i>J. Controlled Release</i> , 5:13-22 (1987).
		MATHIOWITZ, et al., "Novel Microcapsules for delivery systems", <i>Reactive Polymers</i> , 6:275-83 (1987).
		MULLIGAN, "The basic science of gene therapy", <i>Science</i> , 260(5110):926-32 (1993).
		NABEL, et al., "Direct gene transfer with DNA-liposome complexes in melanoma: expression, biologic activity, and lack of toxicity in humans", <i>Proc Natl Acad Sci U S A.</i> , 90(23):11307-11 (1993).
		NICOLAU, et al., "In vivo expression of rat insulin after intravenous administration of the liposome-entrapped gene for rat insulin I", <i>Proc Natl Acad Sci U S A.</i> , 80(4):1068-72 (1983).
		PARTRIDGE, "Gene therapy. Muscle transfection made easy" <i>Nature</i> , (6338):757-8 (1991).
		ROSENBERG, et al., "Use of tumor-infiltrating lymphocytes and interleukin-2 in the immunotherapy of patients with metastatic melanoma. A preliminary report", <i>N Engl J Med.</i> , 319(25):1676-80 (1988).
		SALIB, et al., "Utilization of sodium alginate in drug microencapsulation", <i>Pharmazeutisch Industrie</i> , 40(11A):1230-34 (1978).
		SAWHNEY, et al., "Bioerodible hydrogels based on phtopolymerized poly(ethylene glycol)-co-poly(α -hydroxy acid) diacrylate macromers", <i>Macromolecules</i> , 26:581-7 (1993).
		TAI, et al., "Microencapsulation of recombinant cells: a new delivery system for gene therapy", <i>FASEB J.</i> , 7(11):1061-9 (1993).

Examiner's Signature	<i>Maria Leavitt</i>	Date Considered	03-20-06
----------------------	----------------------	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-95)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/663,265
Sheet	6	of	6	Filing Date	September 16, 2003
				First Named Inventor	Edith Mathiowitz
				Group Art Unit	1633
				Examiner Name	Maria Gomez Leavitt
				Attorney Docket Number	BU MAT1993-04fDIV3CON2

OTHER ART - NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		ULMER, et al. "Heterologous protection against influenza by injection of DNA-encoding a viral protein", <i>Science</i> , 259(5102):1745-9 (1993).
		VERMA and SOMIA, "Gene therapy— premises, problems and prospects" <i>Nature</i> , 389(6648):239-42 (1997).
		WILSON, "Cystic fibrosis. Vehicles for gene therapy" <i>Nature</i> , 365(6448):691-2 (1993).
		WIVEL, et al., "Germ-line gene modification and disease prevention: some medical and ethical perspectives", <i>Science</i> , 262(5133):533-8 (1993).
		WOLFF, et al. "Direct gene transfer into mouse muscle in vivo" <i>Science</i> , 247(4949 Pt 1):1465-8 (1990).
		YANG, "Gene transfer into mammalian somatic cells in vivo", <i>Critical Revies in Biotechnology</i> , 12(4):335-356 (1992).

Examiner's Signature	<i>Maria Leavitt</i>	Date Considered	03-20-06
----------------------	----------------------	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.